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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,045	05/12/2000	SE-JIN LEE	JHU1440-1	1418

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EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/485,045	LEE ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

--The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

THE REPLY FILED 11 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *2,4-11,53 and 55*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Applicant argues that GDF-16 has a well established utility because it could be used to detect ebaf-expressing tumors. Applicant draws the parallel with a monoclonal antibody against a receptor. Applicant additionally cites the utlility guidelines which state that, for example, a protein may have utility if it is determined that increased levels are indicative of heart disease. Applicant additionally argues that the specification asserts that GDF-16 is aTGF-beta family member and likedly to be associated with cell proliferative disorders, and further that it can be used to detect a close family member. Applicant further asserts that the literature indicates that TGF-beta family members have the utilites disclosed in the specification. Applicant reiterates that GDF-16 can be used to detect a cell proliferative disorder via detection of ebaf. Appicant argues that in consequence the invention is enabled.

Applicant's arguments have been fully considered but have not been found to be persuasive. Detection of ebaf is not, as Appicant argues, a "well-established utlility". A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. No such properties are disclosed in the specification. There is no mention of the relationship of GDF-16 to ebaf,of disease associated with ebaf, or the use of GDF-16 to detect ebaf. The art further fails to support such utility. Since the polynucleotide itself is novel, it cannot have been known in the art to be useful for detection of ebaf. The propety that is disclosed in the specification that links it to the prior art is merely that is a member of the TGF-beta family, and there are no teachings in the art that TGF-beta members can generally be used to detect tumors by detection of ebaf. The parallel with a monoclonal antibody is not apt. Unlike an antibody raised against a receptor and used to detect such a receptor, when there is a utility associated with detecting the receptor, the disclosed polynucleotide is fortuitously similar to another polynucleotide for which a utility has been disclosed by another,and was not contemplated by Applicant or apparent from the properties disclosed by Appicant. The parallel with a protein useful for detecting heart disease is similarly not appropriate. Applicant has disclosed no such specific and substantial utility and there is no such utility associated with the identification of GDF-16 as a TGF-beta family member. As stated on pp. 3-4 of the office action of 18 November 2002, TGF-beta family members have diverse functions. Similarly, the disclosure that the polynucleotide is a TGF-beta family member that may be associated with cell proliferative disorders fails to endow it with a utility; there is no disorder that is readily identifiable from the identification of GDF-16 as being a member of this family. Thus, since detection of a malignant disorder by detection of ebaf is not disclosed in the specification, and since identification as a TGF-beta family member does not render such a use apparent or implied and does not endow the polynucleotide with any other utility, the invention lacks a specific and substantial utility. Further, since the invention lacks utility, it also lacks enablement under 35 U.S.C. 112, first paragraph..